

Risk Assessment vs Risk Management: The European Food Safety Authority and Competent Authorities

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Food safety hazards

- May 2011 Germany
- Shiga toxin-producing *E. coli* (STEC) O104:H4
- 4000 people ill
- More than 56 deaths
- Second cluster in Bordeaux-France caused by the same strain
- Sprouted seeds

Risk Analysis

■ Risk assessment:

A scientifically based process consisting of the following steps:

- Hazard identification;
- Hazard characterization;
- Exposure assessment;
- Risk characterization.

Risk Analysis

■ Risk management:

Weighing policy alternatives in consultation with all interested parties, considering:

- Risk assessment
- Other factors relevant for the health protection of consumers and for the promotion of fair trade practices,
- Selecting appropriate prevention and control options.

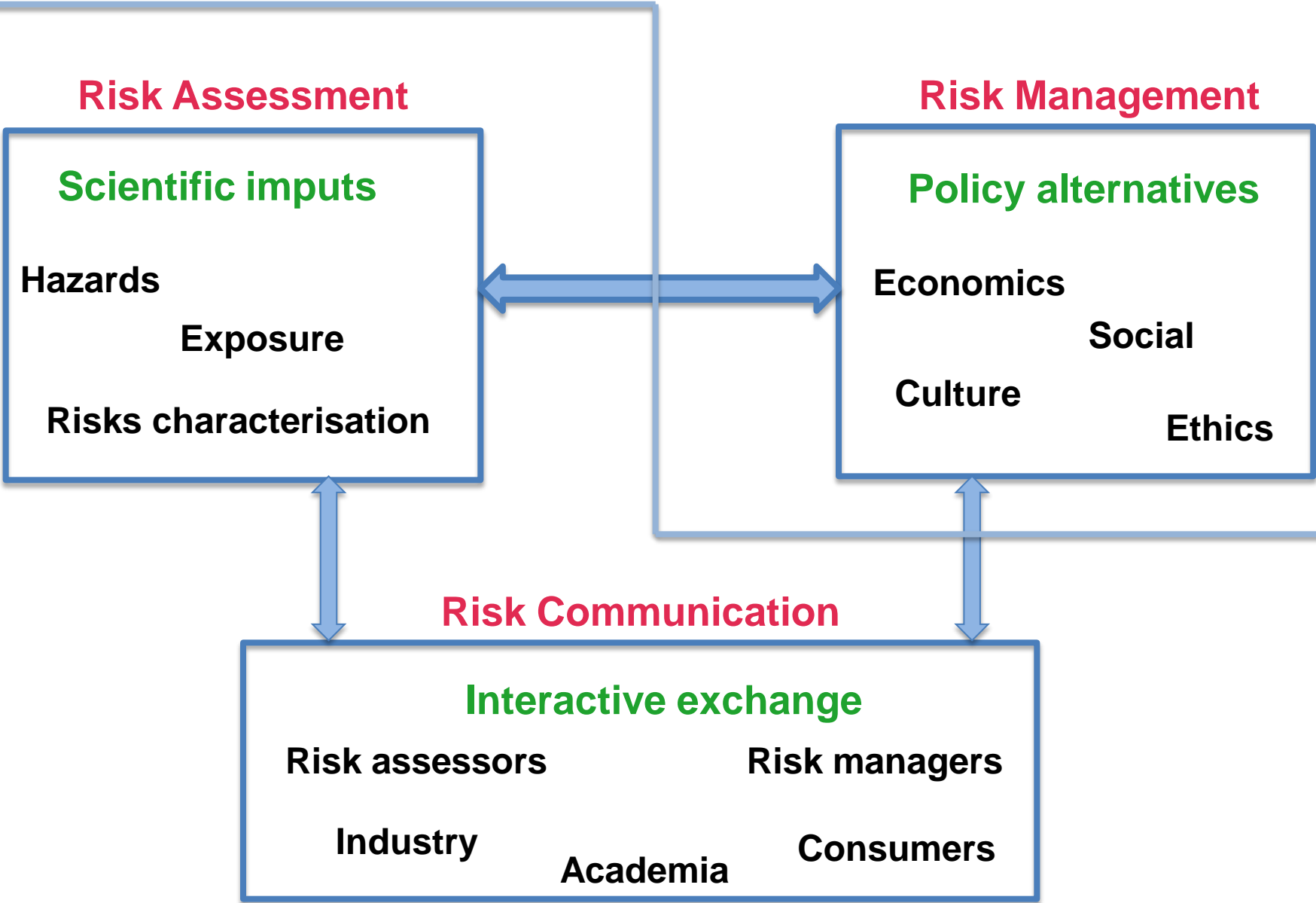
Risk Analysis

■ Risk communication:

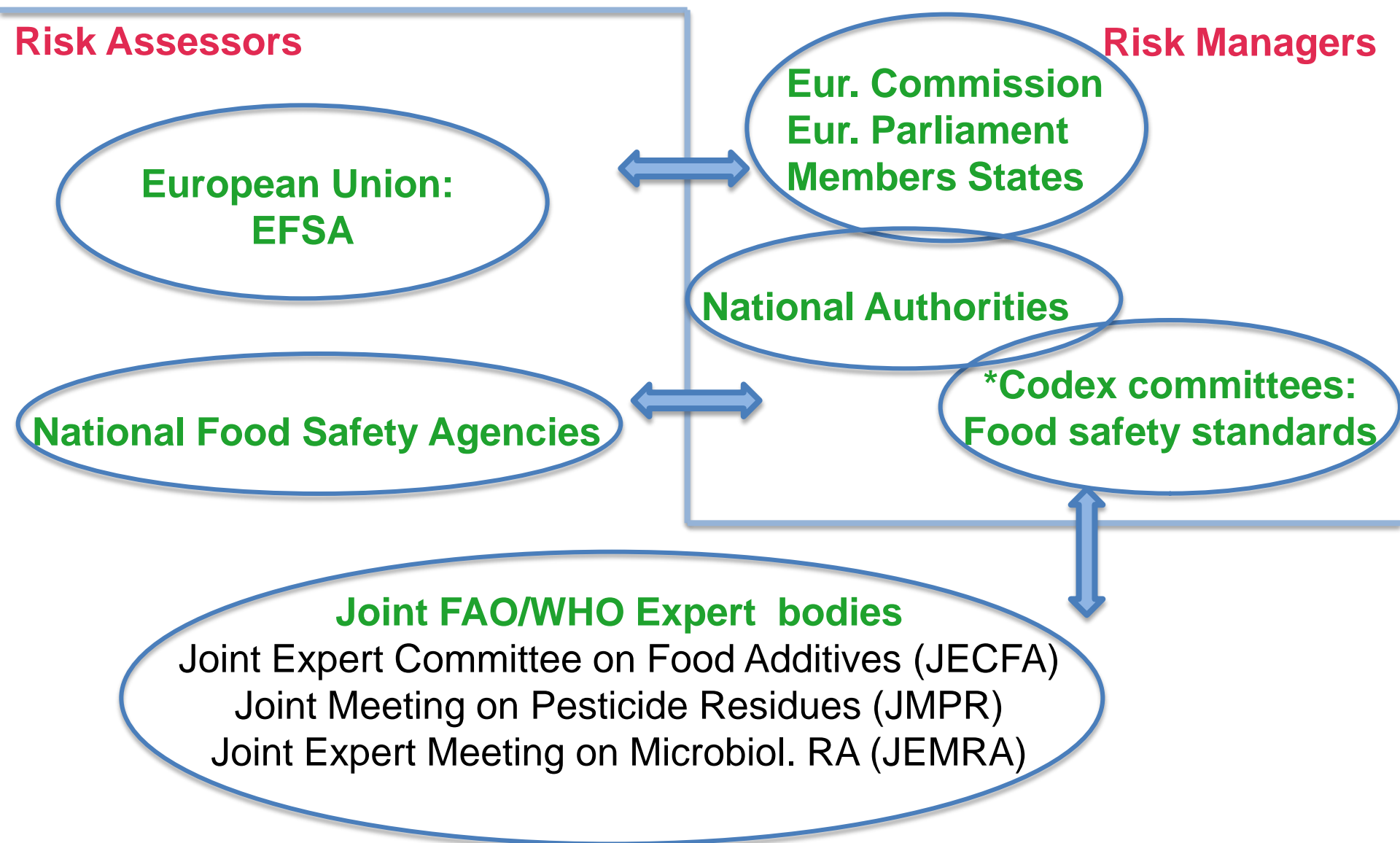
Interactive exchange of information throughout the risk analysis process :

- Risk, risk-related factors and risk perceptions,
- Among risk assessors, risk managers, consumers, industry, the academic community and other interested parties,
- Including the explanation of risk assessment findings and the basis of risk management decisions.

RISK ANALYSIS



Food safety risk analysis is carried out by national, regional and international food safety authorities



Risk Management

- Internationally, *Codex committees that recommend food safety standards (Committees on Food Hygiene, Meat Hygiene, Food Additives, Contaminants, Pesticide Residues, and Residues of Veterinary Drugs in Foods)
- National authorities are responsible for ensuring food safety standards are respected by operators.

EFSA

- EFSA is an independent European agency funded by the EU budget
- Operates separately from the Risk Managers: European Commission, European Parliament and EU Member States

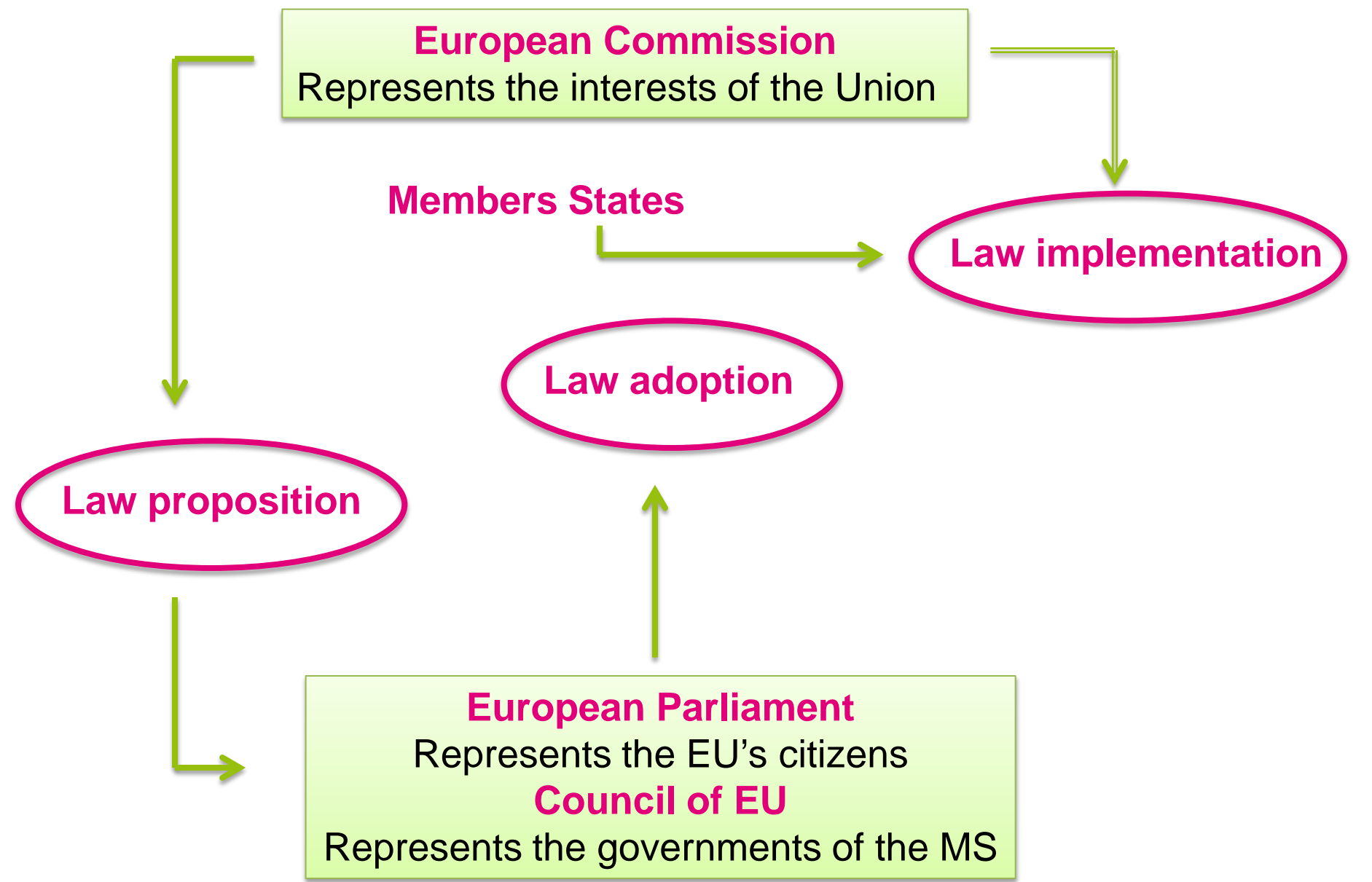
➔ Functional separation between Risk assessment and Risk management

- On the requests for scientific advice from risk managers
- On its own initiative

Missions of EFSA

- Independant information and communication on risks associated with de food chain
- Sc advice and technical support for the Community's legislation and policies on food and feed safety issues
- Sc advice and technical support on human nutrition and assistance concerning communication on nutritional issues within the framework of the community health programme
- Sc opinion on other matters related to animal health and welfare and plant health

EU Legislation



EFSA Scientific Panels/Units

- Risk assessment and scientific assistance
- Scientific evaluation of regulated products
- Science strategy and coordination

Risk assessment and scientific assistance

PANELS

Animal health and welfare (AHAW)

Biological hazards (BIOHAZ)

Contaminants in the food chain (CONTAM)

Plant health (PLH)

UNITS

Biological monitoring (BIOCONTAM)

Evidence management (DATA Unit)

Assessment and methodological support (AMU)

Scientific evaluation of regulated products

PANELS

Genetically modified organisms (GMO)

Dietetic products, nutrition and allergies (NDA)

Food additives and nutrient sources added to food (ANS)

Food contact materials, enzymes, flavourings and processing (CEF)

Additives and products or substances used in animal feed (FEEDAP)

Plant protection products and their residues (PPR)

UNITS

Biological monitoring (BIOCONTAM)

Evidence management (DATA Unit)

Assessment and methodological support (AMU)

Science strategy and coordination

SCIENTIFIC COMMITTEE

Scientific Committee and Emerging risks Unit
Chairs of panels

UNITS

Advisory forum and scientific cooperation (AFSCO)

Individual Experts

Expert database (4000)



EFSA

Scientific Committee

Scientific panels

Working groups

EFSA networks



Stakeholder consultative platform:

- Grants/contracts
- Support projects on RA

EU Institutions

European Medicines Agency
European Chemical Agency
EC Diseases and Control
EC Joint Research Centre



Advisory Forum:

Heads of national Authorities

- Advice on sc matters
- Emerging risks
- Coordination of R. Com.

Members states:

National Authorities
of Food Safety

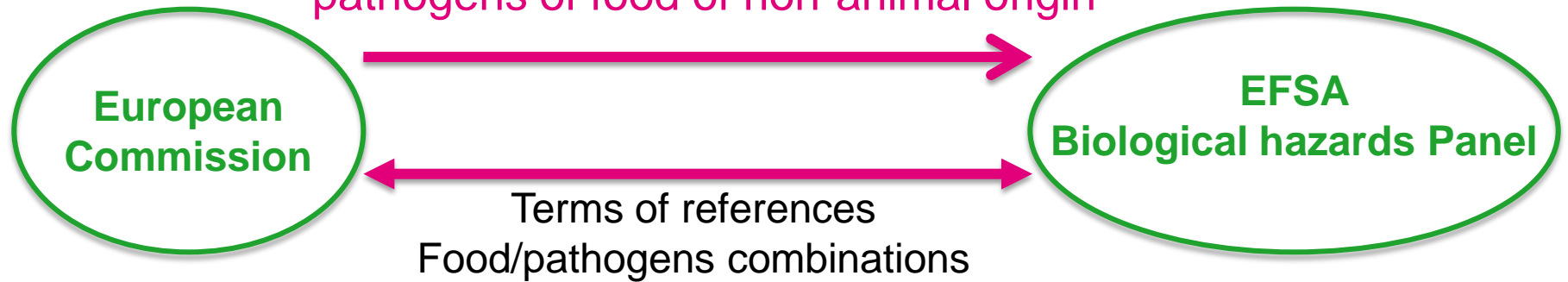


Focal points:

Share information
RA expertise
Collection of data



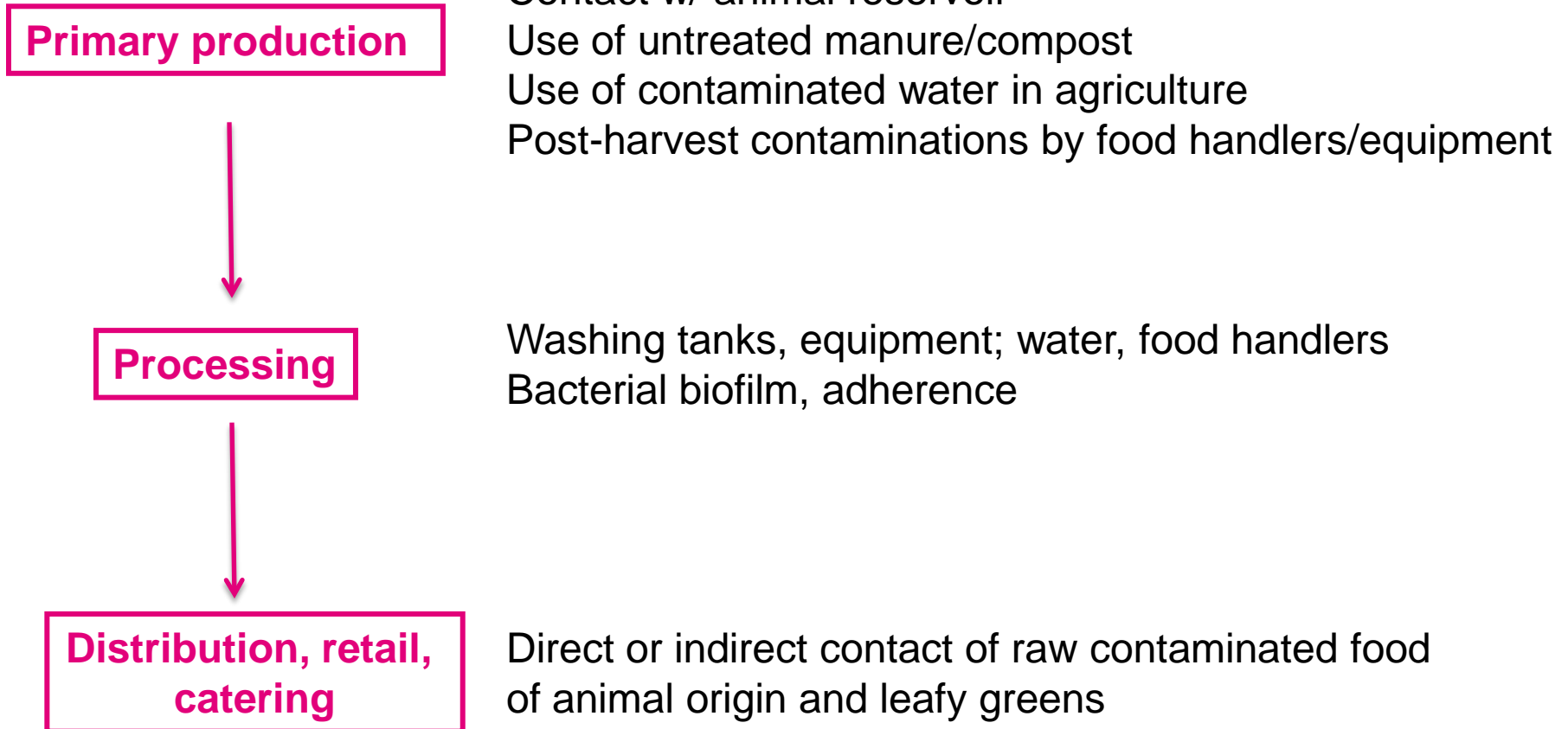
Sc opinion on the public health risk/
pathogens of food of non-animal origin



Risks of *Salmonella* and Norovirus in leafy green eaten raw salad

- 1/ Identify the main risk factors of contamination
- 2/ Recommend possible mitigations and assess their efficiency
- 3/ Recommend microbiological criteria for *Salmonella* and Norovirus in leafy greens

1/ Main risk factors for *Salmonella*



2/ Recommend mitigations

Farm



Food safety management systems : GAP, GHP, GMP

Evaluation of farm environment

Water treatment and sufficient drainage

Testing faecal indicators for irrigation water

Hygiene training to handlers

Labelling for consumers (shelf-life indicators, preparation...)

Fork

3/ Recommend microbiological criteria

- No microbiological criteria at the primary production
- **Hygiene Criteria** to verify GAP/GHP: *E. coli*
Functioning at pre-harvest, harvest and on farm post harvest production prior to processing
- **Process Hygiene Criterion:** *E. coli*
Indication on GAP, GHP, GMP, HACCP implementations
- **Food Safety Criterion:**
 - Absence of *Salmonella* on leafy greens intended to be eaten raw as salad
 - Testing for *Salmonella* in cases indicating failing of GAP, GHP, GMP or HACCP programmes

Risk management

- Regulation and Control
- Other legitimate factors relevant to the matter under consideration should be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
- Precautionary principle is applied in risk management decisions when appropriate

Risk management

- General Food Law (Regulation EC N° 178/2002)
- Regulatory aspects:
 - Legal framework for food safety
 - Legal framework for animal feed
 - Animal health and welfare
 - Holistic approach towards hygiene
 - Limits of contaminants and residus
 - Novel food
 - Additives, flavourings, packaging and irradiation
 - Emergency measures
 - Decision making process to ensure efficacy, transparency and rapidity

Risk management

- Business operators at all stages of production, processing and distribution should ensure that foods or feeds satisfy the requirements of food law
- MS enforce food law and verify that the relevant requirements of food law are fulfilled by food and feed business operators
 - **System of official controls and inspections**
 - **Monitoring and surveillance programmes**
- Measures and penalties applicable to infringements of food and feed law
 - **Effective, proportionate and dissuasive**

Examples of regulations

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Examples of Risk management options

- Ban from an imported food (prohibited ingredient, high levels of pathogens)
- Set MRL for chemicals (pesticides, antibiotics); re-evaluation of MRL
- Prohibition of some food additives
- Authorisation or not of GMOs
- Labelling, Traceability
- Rapid alert system covering food and feed.

Conclusion

■ Risk Assessors

- **Work independently, openly and transparently**
- **Functional separation with Risk Managers**

■ Risk Managers

- **Efficient and commensurate regulations and controls**
- **Appropriate sanctions in cases of non compliance**

■ Risk communication

- **Interactive and transparent process involving all interested parties**